

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of continuous care model and routine care on self-efficacy of patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

To determine the effect of using the contentious care model on the self-efficacy of patients with COPD

Design

Randomized double blind clinical trial with control group and parallel group design, on 84 patients. For randomization, Randomizer will be used.

Settings and conduct

Research environment: Internal ward of all educational and medical centers of Gorgan, includes 5Azar and Sayyad Medical and Educational Centers; Study population: All patients with chronic obstructive pulmonary disease; Type of blinding: Double blind; Method of blinding: Blinding will be done for patients. Also the researcher and the outcome assessor will be also unaware of the allocation of patients into the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Able to write and read; ability to communicate; confirmation of the diagnosis of COPD by a physician; ability to perform the daily activities: history of hospitalization at least once with a diagnosis of COPD; having a smart phone. Non-inclusion criteria: Having malignant disease and psychiatric disorders; history of participating in educational program with similar content

Intervention groups

Intervention group: Patients with chronic obstructive pulmonary disease under follow-up care; Control group: Patients with chronic obstructive pulmonary disease under routine care

Main outcome variables

Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140412017237N13**

Registration date: **2021-09-24, 1400/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-24, 1400/07/02**

Update count: **0**

Registration date

2021-09-24, 1400/07/02

Registrant information

Name

Mahnaz Modanloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3245 6900

Email address

modanloo.mahnaz@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of continuous care model and routine care on self-efficacy of patients with chronic obstructive pulmonary disease

Public title

Continuous care and self-efficacy of patients with COPD

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to write and read Ability to communicate Ability to perform the daily activities Having a smart phone
Obtaining low and medium scores from the self-efficacy questionnaire

Exclusion criteria:

Lack of known psychiatric disorder History of participation in an educational course with the same content

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

By referring to the Randomization.com website and using the block randomization method (block of size 4), a list of random numbers is produced by one of the members of the research team who will not aware of the process of entering the groups (sample size of 84 people, in two groups A - B). Then the letters A and B will be written on the cards and placed in the sequentially numbered, sealed, opaque envelopes (1 to 84). After checking the inclusion criteria, the participants will receive the relevant envelope, respectively, and they will be allocated into two intervention (A) and control (B) groups according to the card in the envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind trial. Blinding will be done for patients. Also the researcher and the outcome assessor will be also unaware of the allocation of patients into the groups. In this study for random sequence generation, 84 eligible patients will be recruit using Permuted Block Randomization (25 blocks of size 4) through Randomization.com. in order to conceal of sequence of randomization, based on a created list, A (for intervention group) and B (for control group) letter will be written on cards and the they will put in the sequentially numbered, sealed, opaque envelopes. Then the envelopes will be numbered from 1 to 84 and will consider for eligible patients sequentially that they will be close till applying intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Golestan University of Medical Sciences

Street address

Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-07-18, 1400/04/27

Ethics committee reference number

IR.GOUMS.REC.1400.101

Health conditions studied**1****Description of health condition studied**

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.9

ICD-10 code description

CHRONIC OBSTRUCTIVE PULMONARY DISEASE, UNSPECIFIED

Primary outcomes**1****Description**

The level of Self-efficacy

Timepoint

Before intervention, immediately after intervention and one months after intervention

Method of measurement

COPD Self-Efficacy Scale

Secondary outcomes**1****Description**

Number of rehospitalization

Timepoint

Record the number of readmissions of patients two and

three months after discharge
Method of measurement
Patient clinical information registration form

Intervention groups

1

Description

Intervention group: The patients in intervention group will access to the Link of educational content in the developed site. The educational content consists of a lung rehabilitation program for patients with chronic obstructive pulmonary disease that will be implemented face-to-face for 2 months based on 4 steps of continuous care model including Orientation, Sensitization, Control and Evaluation. The follow up will be done weekly for 5 weeks.

Category

Behavior

2

Description

Control group: Patients in control group will receive routine care without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Medical and Educational Center

Full name of responsible person

Ali Ariannia

Street address

6th Azar, 5 Azar Street, Gorgan

City

Gorgan

Province

Golestan

Postal code

4917763681

Phone

+98 17 3222 0561

Fax

+98 17 3222 8363

Email

ariannia@goums.ac.ir

Web page address

http://goums.ac.ir

2

Recruitment center

Name of recruitment center

Sayyad Medical and Educational Center

Full name of responsible person

Alireza Norouzi

Street address

Sayad Shirazi St.

City

Gorgan

Province

Golestan

Postal code

4917867439

Phone

+98 17 3226 1175

Email

sayad@goums.ac.ir

Web page address

http://goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Street address

Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 1660

Fax

+98 17 3245 1657

Email

honarvar@goums.ac.ir

Web page address

http://goums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mahnaz Modanloo

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

Street address

Nursing Research Center, Golestan University of Medical Sciences, Hirkan Boulevard

City

Gorgan

Province

Golestan

Postal code

4917136536

Phone

+98 17 3245 6900

Fax

+98 17 3245 5171

Email

modanloo.mahnaz@goums.ac.ir

Web page address

<http://goums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Shahab Eskandari nezhad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Department of Internal Medicine, Faculty of Medicine, Golestan University of Medical Sciences

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3222 0561

Fax

+98 17 3245 2225

Email

dr.eskandari@goums.ac.ir

Web page address

<http://goums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mahsa Mehdizadeh

Position

Ms Student of Critical Nursing Care

Latest degree

Bachelor

Other areas of specialty/work

Critical Care Nursing

Street address

Faculty of Nursing and Midwifery, Golestan University of Medical Sciences, Hirkan Boulevard, Gorgan

City

Gorgan

Province

Golestan

Postal code

4917136536

Phone

+98 17 3245 6900

Fax

+98 17 3245 5171

Email

mahsamahdizadeh1398@gmail.com

Web page address

<http://goums.ac.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified IPD will be shared.

When the data will become available and for how long

6 months after publication the data files will be available.

To whom data/document is available

The data will be shared for people working in academic institutions.

Under which criteria data/document could be used

Meta analyses on data is permitted.

From where data/document is obtainable

Please contact to person responsible for scientific

inquiries.

What processes are involved for a request to access data/document

The data will be available through email.

Comments

Please contact to both email address:
modanloo.mahnaz@goums.ac.ir
modanloo.mahnaz@gmail.com